UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WISCONSIN

JAMES SHERMAN JOHNSON, Individually, DIAMOND JOHNSON, Individually, and KAREN MARIE HAYDEN-JEFFERSON As Administrator of the ESTATE OF JAMES HAYDEN and as Next Friend to the minor Plaintiffs,

Plaintiffs,

v.

Case No. 12-cv-772-pp

MYLAN INC., MYLAN PHARMACEUTICALS, INC., MYLAN TECHNOLOGIES, INC, JOHN DOE MANUFACTURERS A-Z, and JOHN DOE DISTRIBUTORS A-Z,

Defendants.

**DECISION AND ORDER GRANTING DEFENDANTS' MOTION FOR SUMMARY JUDGMENT**

This is a products liability action in which the plaintiffs allege that a transdermal fentanyl patch manufactured by defendant Mylan Technologies, Inc. malfunctioned and caused the death of James Hayden. Earlier in this litigation, the court dismissed a number of the plaintiffs' claims, leaving only their design and manufacturing defect claims remaining. After the court granted the defendants' motion to exclude the testimony of the plaintiffs' expert witness, the plaintiffs elected to proceed on a "malfunction theory" under the doctrine of *res ipsa loquitur*. Collectively, the Mylan defendants have moved for summary judgment. The court held oral arguments on Mylan's motion on

March 9, 2015. Upon review of the record, the parties' submissions, and the oral arguments presented, the court concludes that summary judgment is appropriate because there is no genuine dispute as to any issue of material fact, and the doctrine of *res ipsa loquitur* is not applicable based on the facts of the case. For the reasons discussed below, the court grants Mylan's motion.

## I. BACKGROUND

The parties agree on the following facts. Hayden was diagnosed with sickle cell anemia when he was eleven months old, and he was twenty-four years old at the time of death. Pls.' Resp. to Defs.' Stm. of Proposed Material Facts, Dkt. No. 40, ¶12. On the morning of October 29, 2007, Hayden went to the emergency department at Kenosha Memorial Hospital, complaining of sickle cell pain and difficulty breathing due to nasal congestion. Id., ¶14. Dr. Suzanne Siegel initially administered I.V. fluids, Demerol and Benadryl. Id., ¶14-15. After Dr. Siegel administered those medications, she ordered a 100 mcg fentanyl patch[1], which was applied to Hayden's right arm. Id., ¶16.

Hayden returned home and showed no signs or symptoms of overmedication. Id., ¶17. He showed no such signs as late as 5:00 a.m. on October 30, 2007, approximately 16 hours after the patch was applied, which is consistent with the delivery of fentanyl at the rate it was designed to release.

[1] The fentanyl patch at issue is the Mylan Fentanyl Transdermal System, a generic pharmaceutical product approved by the Food and Drug Administration for the treatment of persistent, moderate-to-severe chronic pain. Dkt. No. 40, ¶9. Mylan Technologies Inc. developed and manufactures the patch, which is distributed by Mylan Pharmaceuticals, Inc. Dkt. No. 5, ¶15. Mylan Technologies Inc. and Mylan Pharmaceuticals, Inc. are wholly owned subsidiaries of Mylan Inc. Dkt. No. 9. Collectively, the Mylan defendants are referred to in this decision and order as "Mylan."

Id. At approximately 2:32 p.m. on October 30, 2007, Hayden was found unresponsive and not breathing. Id., ¶18. Following CPR efforts, he was transported to the Kenosha Medical Center and was pronounced dead that day. Id. After performing an autopsy and receiving toxicology results from a postmortem blood draw, medical examiner Dr. Mary Mainland listed Hayden's cause of death as "Fentanyl Toxicity," based on the toxicology analysis that showed a postmortem fentanyl concentration of 30 mg/ml. Id., ¶19. The plaintiffs allege that Hayden's death was the result of an allegedly defective fentanyl patch, designed, manufactured and distributed by the Mylan defendants. Id., ¶3.

The fentanyl patch applied to Hayden's arm was discarded following the autopsy, per the standard protocol of Dr. Mainland's office. Id., ¶31. Dr. Mainland testified at her deposition that nothing uncovered during her investigation indicated that there was any deficiency or problem with the fentanyl patch. Id., ¶ 20. However, her finding that the cause of Hayden's death was related to fentanyl did not indicate that there was a defect or malfunction in the patch. Id. The postmortem concentration of fentanyl in the blood did not reflect the concentration of the drug in the systemic circulation during lifetime, and the exact concentration of fentanyl in Hayden's body at the time of his death is unknown. Id., ¶21. That is because fentanyl may undergo postmortem redistribution, which is the process by which a substance stored in the body tissue at relatively high concentrations while a person is living migrates elsewhere in the body (such as to the blood) after death. Id., ¶22.

Postmortem redistribution creates the potential for artificially elevated blood levels, and postmortem redistributive changes for fentanyl can be significant. Id., ¶23. Accordingly, one cannot infer or suggest that an elevated postmortem fentanyl level proves a causal connection to a defect in a transdermal drug delivery system, because postmortem fentanyl levels are not representative of antemortem fentanyl levels. Id., ¶24.

On November 13, 2012, the court granted Mylan's Partial Motion to Dismiss, dismissing the plaintiffs' fraud, misrepresentation and failure-to-warn claims. Id., ¶4. The plaintiffs now are proceeding only on their claims of design defect and manufacturing defect. Id. In support of these claims, the plaintiffs proffered the testimony of a single expert, Dr. Mark Dershwitz, who intended to base his opinion that there was a defect or malfunction in the fentanyl patch on (a) Dr. Mainland's s determination that Hayden's death was caused by fentanyl toxicity and (b) Hayden's postmortem blood concentration of fentanyl. Id., ¶27. On August 6, 2014, the court granted Mylan's motion to exclude Dr. Dershwitz's testimony, based on the court's determination that Dr. Dershwitz "ha[d] nothing to support his conclusion of patch failure – no method, test or scientific process supports [his opinion]." Id., ¶7. As a result of this decision, the plaintiffs now have no expert witness to testify regarding any alleged manufacturing or design defect or malfunction in the fentanyl patch Hayden wore. Id., ¶¶29-30.

## II. ANALYSIS

This is a diversity action. The plaintiffs are Wisconsin citizens. Mylan, Inc. is a Pennsylvania corporation with its principal place of business in Canonsburg, Pennsylvania. Mylan Pharmaceuticals, Inc., is a West Virginia corporation with its principal place of business in Morgantown, West Virginia. Mylan Technologies, Inc. is a West Virginia corporation with its principal place of business in St. Albans, Vermont. The court applies federal procedural law and state substantive law, including the state's choice of law rules. Allen v. Cedar Real Estate Grp., LLP, 236 F.3d 374, 380 (7th Cir. 2001) (citing Erie R.R. v. Tompkins, 304 U.S. 64, 78, 58 S. Ct. 817 (1938)).

Under Wisconsin law, the law of the forum state governs a tort case unless it is clear that nonforum contacts are more significant. State Farm Mut. Auto. Ins. Co. v. Gillette, 251 Wis. 2d 561, 587-88, 641 N.W.2d 662, 675-76 (2002). This case has a significant relationship to Wisconsin—Hayden's illness, treatment and death occurred in Wisconsin. The parties do not dispute that Wisconsin substantive law applies, and when that is so, "the default rule is to apply the law of the state where the district court sits." Schultz v. Akzo Nobel Paints, LLC, 721 F.3d 426, 433 (7th Cir. 2013). Therefore, the court applies Wisconsin substantive law.

### A. Applicable Standards

#### *1. Summary Judgment*

A court must grant summary judgment when there is no genuine dispute as to any material fact and the moving party is entitled to judgment as a matter

of law. Fed. R. Civ. P. 56(a); Celotex Corp. v. Catrett, 477 U.S. 317, 322, 106 S. Ct. 2548 (1986). A court appropriately grants summary judgment "against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." Id. The "purpose of summary judgment is to pierce the pleadings and to assess the proof in order to see whether there is a genuine need for trial." Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 587, 106 S. Ct. 1348 (1986) (internal quotation marks omitted) (citation omitted). "A party will be successful in opposing summary judgment only when they present definite, competent evidence to rebut the motion." EEOC v. Sears, Roebuck & Co., 233 F.3d 432, 437 (7th Cir. 2000). The nonmoving party is entitled to all reasonable inferences in its favor, but "inferences that are supported by only speculation or conjecture will not defeat a summary judgment motion." Herzog v. Graphic Packaging Int'l, Inc., 742 F.3d 802, 806 (7th Cir. 2014) (quoting Tubergen v. St. Vincent Hosp. & Health Care Ctr., Inc., 517 F.3d 470, 473 (7th Cir. 2008)).

*2. The Doctrine of Res Ipsa Loquitur*

Under §895.047, Wisconsin's products liability statute, a plaintiff must establish the following five elements to prevail: (1) the product is defective in design, manufacture or warnings; (2) the defect rendered the product unreasonably dangerous; (3) the defective condition existed at the time the product left control of the manufacturer; (4) the product reached the user without substantial change in condition; and (5) the defective condition was the

cause of the complained-of harm. Wis. Stat. Ann. §895.047(1)(a)–(e). In this case, however, the plaintiffs explain that they are not attempting to establish liability under §895.047 or "traditional tort causes of action," and they argue that Mylan's arguments under that statute are "entirely moot." Dkt. No. 39, at 5, 10. Instead, they explain that they are proceeding under a "malfunction theory" based on the doctrine of *res ipsa loquitur*. Id., at 5.

Wisconsin courts characterize the doctrine of *res ipsa loquitur* as a rule of circumstantial evidence that allows a fact-finder to infer negligence (or in this case, a product defect) in certain fact situations. Milwaukee Metro. Sewerage Dist. v. City of Milwaukee, 267 Wis. 2d 688, 704, 671 N.W.2d 346, 354 (Wis. App. 2003) (citing Lambrecht v. Estate of Kaczmarczyk, 241 Wis. 2d 804, 623 N.W.2d 751 (2001)). The doctrine "is meant to bridge an evidentiary gap when an injury could not have happened but for the defendant's negligence." Buechel v. United States, 746 F.3d 753, 765 (7th Cir. 2014). The doctrine is appropriate in cases where:

> (a) either a layman is able to determine as a matter of common knowledge or an expert testifies that the result which has occurred does not ordinarily occur in the absence of negligence, (b) the agent or instrumentality causing the harm was within the exclusive control of the defendant, and (c) the evidence offered is sufficient to remove the causation question from the realm of conjecture, but not so substantial that it provides a full and complete explanation of the event.

Peplinski v. Fobe's Roofing, Inc., 193 Wis. 2d 6, 17, 531 N.W.2d 597, 601 (1995).

Under Wisconsin law, "[a]n application of the doctrine based on common knowledge is allowed only when the occurrence clearly 'speaks for itself.'" Kelly v. Hartford Cas. Ins. Co., 86 Wis. 2d 129, 134, 271 N.W.2d 676, 679 (1978) (citation omitted). A court may apply *res ipsa loquitur* in the "rare instances" in which "circumstantial evidence may produce reasonable inferences upon which a jury may reasonably find that a defendant manufactured a product containing a defect." Whitted v. Gen. Motors Corp., 58 F.3d 1200, 1208 (7th Cir. 1995). In a products liability action, *res ipsa loquitur* allows a jury to infer that a defect existed when the product left the manufacturer's control, and that the defect caused the product to fail, if plaintiff establishes the following three elements: (1) the problem ordinarily only occurs if there is negligence; (2) the plaintiff was using the product properly; and (3) the plaintiff negates other possible causes of the product's failure. Jagmin v. Simonds Abrasive Co., 61 Wis. 2d 60, 71, 211 N.W. 810, 817 (1973).

For the doctrine to apply, "it must be obvious to the trier of fact that an accident of the type that injured the plaintiff rarely occurs in the absence of negligence." Clifford v. Crop Prod. Servs., Inc., 627 F.3d 268, 273 (7th Cir. 2010) (citing Smoot v. Mazda Motors of Am., Inc., 469 F.3d 675, 679–80 (7th Cir. 2006)). "A typical example is where, after surgery, a plaintiff discovers that a surgeon's sponge was left inside his abdomen. In such a case, the trier of fact can infer without considering additional evidence that someone in the operating room was negligent." Clifford, 627 F.3d at 273 (internal citation omitted).

Expert testimony is required if the issue to be decided by the jury is outside the common knowledge of a layman.

> There may be cases where the issue of causation, like the issue of negligence, involves technical, scientific or medical matters which are beyond the common knowledge or experience of jurors and without the aid of expert testimony the jury could only speculate as to what inferences to draw if it were left to determine the issue. The lack of expert testimony in such cases results in an insufficiency of proof.

City of Cedarburg Light & Water Comm'n v. Allis-Chalmers Mfg. Co., 33 Wis. 2d 560, 568 149 N.W.2d 661, 662 (1967).

Wisconsin courts have concluded that *res ipsa loquitur* is inapplicable in medical malpractice cases in which negligence or causation is not within a lay jury's common knowledge. See, e.g., Kelly, 86 Wis. 2d at 134, 271 N.W.2d at 679 (concluding that the process of rectal catheterization is not "so well known and understood by lay people that it permits a jury to infer negligence on the part of the doctors from any fact of common knowledge possessed by laymen."); Ollman v. Wis. Health Care Liab. Ins. Plan, 178 Wis. 2d 648, 667, 505 N.W.2d 399, 405 (Ct. App. 1993) (explaining that the causal relationship between abdominal surgery, a fecal spill, the premature cessation of antibiotics, and an abcess "requires a determination that is beyond the ken of the average layperson.").

B. There Is No Genuine Dispute of Material Fact for Trial

The plaintiffs bear the burden of demonstrating the existence of admissible record evidence that creates a genuine issue of fact as to whether the patch Hayden wore was defective or malfunctioned, causing his death. The

plaintiffs and Mylan agree that (1) fentanyl may undergo postmortem redistribution, which may create the potential for artificially elevated postmortem blood levels, and that (2) as a result, an elevated postmortem fentanyl level cannot be used to suggest or infer a defect in a transdermal drug delivery system, because postmortem fentanyl levels are not representative of antemortem fentanyl levels. Dkt. No. 40, ¶¶22-23. Despite agreeing with these facts, the plaintiffs argue that the level of fentanyl found in Hayden's blood after his death "is prima facia [sic] evidence" that the fentanyl patch Hayden wore was defective. Dkt. No. 39, at 12. But the level of fentanyl found in Hayden's postmortem blood *cannot* constitute evidence supporting the plaintiffs' contention that the patch was defective or malfunctioned, because the plaintiffs *agree* that Hayden's postmortem fentanyl blood levels might have been "artificially elevated" and "cannot be used to suggest or infer" that the patch was defective.

Given the agreed facts, and the plaintiffs' lack of an expert witness (discussed below), the plaintiffs needed to identify other admissible evidence supporting their contention that the patch was defective or malfunctioned in order to defeat the summary judgment motion. The plaintiffs point to Dr. Mainland's report, which lists the cause of death as "Fentanyl Toxicity," and argue that Dr. Palmer, Mylan's expert witness, could not determine whether and to what extent postmortem redistribution occurred. Dkt. No. 41, ¶¶18-24. The plaintiffs argue that this constitutes substantive circumstantial evidence that creates a factual dispute as to whether Hayden's postmortem fentanyl

levels were caused by a patch defect or postmortem redistribution. Dkt. No. 39, at 9-10, 17. The court disagrees.

Dr. Mainland's report does not create a genuine dispute as to whether the patch was defective or malfunctioned. The plaintiffs agree that "[h]er finding that the cause of death was related to fentanyl does not indicate that there was a defect or malfunction in the patch," and Dr. Mainland testified that there was nothing uncovered during her investigation that indicated that there was any deficiency or problem with the fentanyl patch. Dkt. No. 40, ¶20. Dr. Palmer has proffered an expert opinion explaining that Hayden's elevated postmortem fentanyl blood level was influenced by postmortem redistribution; the plaintiffs' argument that he cannot quantify how much redistribution occurred does not help them establish a patch defect or malfunction, because they have agreed that "postmortem redistributive changes for fentanyl can be significant." Id., ¶23.

The plaintiffs cite two cases involving allegedly defective fentanyl patches to argue that a genuine issue of fact precludes summary judgment, but each of those cases involved genuine disputes of material fact as to *causation*. In Mardegan v. Mylan Inc., No. 10-cv-14285, Dkt. No. 121 (S.D. Fla. Jan. 31, 2012), the plaintiff presented testimony from two experts, a pathologist and toxicologist. Dkt. No. 42-2, at 7-10. Based on the experts' opinion that a defective patch "more likely than not" caused the decedent's death, the court denied Mylan's motion for summary judgment and allowed a manufacturing defect case to proceed. Id. 10.

Similarly, in Kunnemann v. Janssen Pharmaceutical Products, L.P., No. 05-cv-3211, 2008 WL 5101116, at *8-12 (N.D. Ill. Dec. 2, 2008), the court denied the defendant's motion for summary judgment because the parties presented conflicting testimony from multiple expert witnesses as to whether a patch defect caused the decedent's death. After comparing the expert testimony on both sides, the court found that "significant issues of material fact exist on causation," including "whether the level of fentanyl in Ms. Kunnemann's blood at the time of the autopsy is indicative of the level of fentanyl in her blood at the time of her death[.]" Id. at 12.

In this case, the plaintiffs and Mylan have agreed on the record that the level of fentanyl in Hayden's blood does not indicate the level in his blood at the time he died, and cannot be used to infer the patch was defective. If this case were to proceed to trial, the plaintiffs would ask a jury to make that very same inference, which would amount to speculation about matters beyond a layperson's common knowledge. The plaintiffs have cited no admissible record evidence to create a genuine issue as to whether the patch was defective or malfunctioned and caused Hayden's death.

C. The Plaintiffs Cannot Establish the Fentanyl Patch at Issue Was Defective without Expert Testimony

The plaintiffs nonetheless ask to proceed to trial under the doctrine of *res ipsa loquitor*. Without expert testimony, the plaintiffs cannot use the *res ipsa loquitur* theory, because the issues are not within a lay jury's common knowledge and general experience. Relying on Jagmin, the plaintiffs contend that "Wisconsin does not require expert testimony in *res ipsa* products liability

cases," Dkt. No. 39, at 19, but that overly broad assertion does not accurately represent Wisconsin law or Jagmin itself. Wisconsin courts do not require expert testimony *as long as* the case involves issues within the general common knowledge of a lay jury. Peplinski, 193 Wis. 2d at 17, 531 N.W.2d at 601; City of Cedarburg, 33 Wis. 2d at 568, 149 N.W.2d at 662; Steinberg v. Arcilla, 194 Wis. 2d 759, 764, 535 N.W.2d 444, 445-46 (Ct. App. 1995); Clifford, 627 F.3d at 273. Under Wisconsin law, products liability cases based on *res ipsa loquitur* are not treated differently from negligence cases, and the doctrine is not applicable if the issues involve matters outside a lay jury's common knowledge.

Jagmin involved injuries caused by a broken grinding wheel. Jagmin, 61 Wis. 2d at 64, 211 N.W.2d at 812. The trial court decided that the jury could not reasonably infer that the grinding wheel was defective, because it had been in use for some time before the accident. Id. at 66-67. 211 N.W.2d at 813-14. The Wisconsin Supreme Court, characterizing the case as "exceedingly close" on the facts, reversed, concluding that the jury could reasonably infer that the wheel was defective based on the evidence adduced at trial. Id. at 77, 211 N.W.2d at 819. Nothing in Jagmin supports the plaintiffs' suggestion that *res ipsa loquitur* can be applied in every product liability case, no matter the complexity of the issues.

In fact, contrary to the plaintiffs' suggestion, in a products liability case governed by Wisconsin law involving an allegedly defective automobile airbag, the Seventh Circuit stated that expert testimony "in a case based on *res ipsa*

*loquitur* might seem mandatory . . . if the inference of negligence from the accident itself was obvious only to an expert." Smoot v. Mazda Motors of Am., Inc., 469 F.3d 675, 680 (7th Cir. 2006). In Smoot, the plaintiffs claimed that, after Ms. Smoot hit a large chunk of asphalt while driving, her car's airbag malfunctioned and deployed improperly, injuring her. The plaintiffs attempted to invoke *res ipsa loquitur* to establish liability, but the district court required them to support their case with expert testimony. As the Seventh Circuit explained, the plaintiffs conceded

> that a 'sudden slowing' in the speed of the car by only 8 m.p.h. would have triggered a properly controlled airbag, and we cannot say as a matter of common sense or common experience that hitting a pothole or a chunk of asphalt could not cause a 'sudden slowing' of the car from 35 to 27 m.p.h.

Id. at 681. By contrast, the court in Smoot suggested the doctrine could have been applicable "had the airbags deployed when Mrs. Smoot parked her car and turned off the ignition, or when while driving steadily she had blown the car's horn." Id. at 680. In this case, as discussed below, the court concludes that the plaintiffs needed to support their claims with expert testimony in order to proceed to trial.

*1. The question of whether Hayden's death was caused by a defective Fentanyl patch is not within a lay jury's common knowledge or general experience.*

This case presents several scientific and medical issues that the court concludes are outside a layman's common knowledge, including: the process of postmortem fentanyl redistribution; whether Hayden's elevated postmortem fentanyl blood levels can be used to establish that the fentanyl patch was

defective, or that it malfunctioned; and whether any such defect or malfunction caused Hayden's death. With the exclusion of Dr. Dershwitz's proffered testimony, the plaintiffs have no expert witness to testify to any of these issues. As the Jagmin court held, it is the plaintiffs' burden to introduce "evidence which affords a reasonable basis for the conclusion that it was more likely than not that conduct of the defendant manufacturer was a substantial factor in the injury." Jagmin, 61 Wis. 2d at 74, 211 N.W.2d at 817. The plaintiffs can proceed on a *res ipsa loquitur* theory only if they can identify evidence that would provide a reasonable basis for a lay jury to conclude, based on general common knowledge, that the fentanyl patch more likely than not was defective.

At oral argument, the plaintiffs' counsel indicated that at trial, the plaintiffs would call Dr. Mainland as a fact witness to discuss the findings which led her to attribute Hayden's death to fentanyl toxicity. He told the court that the facts and Dr. Mainland's testimony, supported by her background and experience, would buttress her opinion that Hayden died of a fentanyl overdose and, in turn, would allow the jury to infer that the fentanyl patch was defective or malfunctioned. But Dr. Mainland testified that that there was nothing uncovered during her investigation of the case that indicated that there was any deficiency or problem with the Mylan fentanyl patch. Dkt. No. 40, ¶20. And, even though she attributed Hayden's death to fentanyl toxicity, Dr. Mainland has not been offered as, or qualified as, an expert who can opine that Hayden's fentanyl patch was defective or malfunctioned. The court concludes that (1) despite Dr. Mainland's conclusion that Hayden died as a result of

fentanyl toxicity, she cannot testify as to whether the fentanyl patch was defective or malfunctioned, and (2) the question of whether the patch was defective or malfunctioned is not a matter in the realm of a layman's general knowledge.

A federal district court in Oklahoma considered a case arising out of similar facts, and reached the same conclusion. In Manous v. Mylan Pharmaceuticals, Inc., 982 F. Supp. 2d 1282 (W.D. Okla. 2013), Carol Manous died while wearing two 100 ng/ml Mylan fentanyl patches. Id. at 1283. A blood sample taken hours after her death indicated a postmortem blood level of 28.1. ng/ml. *Id.* at 1283, n.2. Without conducting an autopsy, the medical examiner determined that Ms. Manous died of acute fentanyl toxicity. Id. at 1283. The plaintiff contended that a manufacturing defect in one or both of the fentanyl patches resulted in the release of excess fentanyl, causing Ms. Manous's death. Id. at 1283. The defendant moved to exclude the testimony of the plaintiff's expert witness, a pharmacist, which that court decided in a separate opinion. Manous v. Mylan Pharma., Inc., 982 F. Supp. 2d 1277 (W.D. Okla. 2013). The court concluded that the pharmacist was not

> the appropriate expert to opine that the fact that the medical examiner determined that Ms. Manous's postmortem blood concentration of Fentanyl was 28.1 ng/ml and caused her death was correct, was not based on postmortem redistribution or that it was the result of a defect in the Mylan Transdermal Fentanyl patches that Mrs. Manous was wearing at the time of her death.[2]

[2] The court noted that even the plaintiff's expert could not identify how the fentanyl patch could have been defective. Manous, 982 F. Supp. 2d at

Id. at 1280.

Having excluded the plaintiff's expert witness, the court granted summary judgment in defendant Mylan's favor, because the plaintiff lacked an expert to explain his contentions regarding the allegedly defective manufacture of the patches, an issue which the court concluded was not within the realm of ordinary experience. Manous, 982 F. Supp. 2d at 1283. The court concluded that "pursuant to Oklahoma law, the elevated fentanyl level in Ms. Manous's blood postmortem is not sufficient to sustain Plaintiff's claims," and that to allow the case to proceed would permit the plaintiff "to rely solely on speculation." Id. at 1284-85.

This case is analogous to Manous, and the court likewise concludes that the plaintiffs cannot proceed to trial under the doctrine of *res ipsa loquitur*. The plaintiffs have no expert witness who can testify that Hayden's fentanyl patch was defective, or that it malfunctioned. Pharmacology, toxicity, and transdermal drug delivery are not matters within common knowledge or ordinary experience.

*2. DiCosolo v. Janssen Pharmaceuticals, Inc. is inapposite and does not establish that summary judgment is inappropriate.*

The plaintiffs argue that expert testimony is not necessary in cases involving alleged defective fentanyl patches, citing DiCosolo v. Janssen Pharmaceuticals, Inc., 951 N.E.2d 1238 (Ill. Ct. App. 2011). DiCosolo was an

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1284. The same is true in this case. The court previously determined that Dr. Dershwitz had "nothing to support his conclusion of patch failure – no method, test or scientific process[.]" Dkt. No. 33, at 4.

Illinois appellate court decision in a wrongful death case involving a different manufacturer of fentanyl patches. It is true that the DiCosolo court, in discussing the Illinois *res ipsa loquitor* case law, stated that, ". . . it is *not* the rule in Illinois that, absent [*res ipsa loquitor*], a case in strict tort liability could be established only through expert testimony." Id. at 1247. But the court went on to say, "The plaintiff may rely on direct or circumstantial evidence to establish his case or on expert testimony . . .; indeed, expert testimony is merely one kind of circumstantial evidence." Id. (quoting Millette v. Radosta, 84 Ill. App. 3d 5, 21 (Ct. App. 1980)).

The plaintiff in DiCosolo had several kinds of direct and circumstantial evidence. The plaintiff established that the fentanyl patch at issue was part of a lot of patches that was subject to recall, because some contained a defect potentially resulting in "increased exposure" to fentanyl, which "can lead to increased drug effect including nausea, sedation, drowsiness, or potentially life-threatening complications." Id., at 1242. The plaintiff presented testimony from an expert witness who

> [had] a Ph.D. in chemical engineering that focused on transdermal drug delivery, . . . studied transdermal drug delivery for more than 20 years, . . . [held] more than 20 patents in the area of transdermal drug delivery, . . . [taught] courses on transdermal drug delivery, . . . [had] published more than 100 articles on transdermal drug delivery, and . . . [sat] on the editorial boards of the two leading journals in the area of drug delivery.

Id. at 1252. The plaintiff's expert "testified at length regarding the numerous bases for his opinion that the patch at issue leaked." Id. The plaintiff further

supported his case with an affidavit stating that he found a "slick film" on his wife's skin, which the plaintiff's expert testified was consistent with a patch failure. Id.

This case presents no such facts. The court concludes that it cannot submit these facts to a jury under the theory of *res ipsa loquitur* based solely on the facts that Hayden had elevated levels of fentanyl in his postmortem blood sample and that Dr. Mainland concluded that he died of fentanyl toxicity.

## III. CONCLUSION

The court concludes that there is no dispute as to any genuine issue of material fact, and that the Mylan defendants are entitled to judgment as a matter of law. Accordingly, the court **GRANTS** Mylan's Motion for Summary Judgment, and **DISMISSES** the plaintiffs' claims against the Mylan defendants.

**ORDERED** at Milwaukee this 1st day of June, 2015.

**HON. PAMELA PEPPER**
**United States District Judge**